By: Howard H.B. No. 243

## A BILL TO BE ENTITLED

1 AN ACT

- 2 relating to the immunization data included in and excluded from the
- 3 immunization registry.
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
- 5 SECTION 1. Section 161.007, Health and Safety Code, is
- 6 amended by amending Subsections (a), (a-2), (b), (b-1), (c), (d),
- 7 and (e) and adding Subsections (e-1), (1), and (m) to read as
- 8 follows:
- 9 (a) The department, for the primary purpose of establishing
- 10 and maintaining a single repository of accurate, complete, and
- 11 current immunization records to be used in aiding, coordinating,
- 12 and promoting efficient and cost-effective communicable disease
- 13 prevention and control efforts, shall establish and maintain an
- 14 immunization registry. The executive commissioner by rule shall
- 15 develop guidelines to:
- 16 (1) protect the confidentiality of patients in
- 17 accordance with Section 159.002, Occupations Code;
- 18 (2) inform the individual or the individual's legally
- 19 authorized representative about the registry and that registry
- 20 information may be released under Section 161.00735;
- 21 (3) [require the written or electronic consent of the
- 22 individual or the individual's legally authorized representative
- 23 before any information relating to the individual is included in
- 24 the registry;

1  $\left[\frac{4}{4}\right]$  permit the individual or the individual's 2 legally authorized representative to request that the individual's information be removed from [withdraw consent for the individual to 3 be included in] the registry; 4 5 (4) provide opportunities for the individual or the 6 individual's legally authorized representative to request removal 7 at any time, including: 8 (A) at the time of the individual's birth if attended by a health care provider who administers immunizations; 9 10 (B) each time the individual receives any immunization administered by a health care provider in this state; 11 12 (C) through electronic submission of a request for removal using a request for removal procedure available on the 13 14 department's Internet website; (D) through submission to the department of a 15 written request for removal; and 16 17 (E) following a natural or man-made disaster; [and] 18 19 (5) ensure that an individual or the individual's legally authorized representative is not required to request 20 21 removal from the registry more than one time and that, after a request for removal is made, the individual's immunization 22 information will not be included in the registry unless the 23 24 individual or the individual's legally authorized representative submits to the department a written request for inclusion of the 25 26 individual's information in the registry; and

(6) include on each immunization record generated by

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- 1 the registry the procedures for requesting removal from the
- 2 registry [<del>determine the process by which consent is verified,</del>
- 3 including affirmation by a health care provider, birth registrar,
- 4 regional health information exchange, or local immunization
- 5 registry that consent has been obtained].
- (a-2) [The written or electronic consent required by 6 7 Subsection (a)(3) for an individual who is 18 years of age or older 8 is required to be obtained only one time and must be received from the individual before the information may be released. 9 10 individual's legally authorized representative or the individual, after the individual has attained 18 years of age, may submit a 11 request [consent] in writing or electronically for the individual's 12 information to be removed from [remain in] the registry. 13 consent of the representative or individual is valid until the 14 15 individual or the individual's legally authorized representative withdraws consent in writing or electronically. The department 16 17 may not include in the registry the immunization information of an individual who is 26 years of age or older until written or 18
- 20 subsection.] The department shall coordinate with the Texas

electronic consent has been obtained as provided by this

- 21 Education Agency to distribute materials described in Section
- 22 161.0095(a)(2) to students and parents through local school
- 23 districts.

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- 24 (b) Except as provided by Section 161.0071, the
- 25 immunization registry must contain information on the immunization
- 26 history that is obtained by the department under:
- 27 (1) this section of each individual for whom

- 1 <u>immunization information</u> [consent] has been obtained, unless the
- 2 individual or the individual's legally authorized representative
- 3 has requested that the individual's information be removed from the
- 4 <u>registry</u> in accordance with guidelines adopted under Subsection
- 5 (a);
- 6 (2) Section 161.00705 of persons immunized to prepare
- 7 for or in response to a declared disaster, public health emergency,
- 8 terrorist attack, hostile military or paramilitary action, or
- 9 extraordinary law enforcement emergency;
- 10 (3) Section 161.00706 of first responders or their
- 11 immediate family members; and
- 12 (4) Section 161.00735 of persons evacuated or
- 13 relocated to this state because of a disaster.
- 14 (b-1) The department shall remove from the registry
- 15 information for any individual for whom [consent has been
- 16 withdrawn. The department may not retain individually identifiable
- 17 information about any individual:
- 18 [(1) for whom consent has been withdrawn;
- 19 [(2) for whom a consent for continued inclusion in the
- 20 registry following the end of the declared disaster, public health
- 21 emergency, terrorist attack, hostile military or paramilitary
- 22 action, or extraordinary law enforcement emergency has not been
- 23 received under Section 161.00705(f);
- 24 [(3) for whom a request to be removed from the registry
- 25 has been received under Section 161.00706(e);
- 26 [(4) for whom consent for continued inclusion in the
- 27 registry following the end of a disaster has not been received under

## 1 Section 161.00735(f); or

- [(5) for whom] a request to remove information from the registry has been received under this subchapter [Section (5)].
- 5 (c) A payor that receives data elements from a health care provider who administers an immunization to an individual younger 6 than 18 years of age shall provide the data elements to the 7 8 department. A payor is required to provide the department with only the data elements the payor receives from a health care provider. A 9 10 payor that receives data elements from a health care provider who administers an immunization to an individual 18 years of age or 11 12 older may provide the data elements to the department. The data elements shall be submitted in a format prescribed by the 13 14 department. [The department shall verify consent before including 15 the reported information in the immunization registry. The department may not retain individually identifiable information 16 17 about an individual for whom consent cannot be verified.
- (d) A health care provider who administers an immunization 18 19 to an individual younger than 18 years of age shall provide data elements regarding an immunization to the department. A health 20 care provider who administers an immunization to an individual 18 21 years of age or older may submit data elements regarding an 22 23 immunization to the department. At the request and with the 24 authorization of the health care provider, the data elements may be submitted through a health information exchange as defined by 25 Section 182.151. The data elements shall be submitted in a format 26 prescribed by the department. A health care provider who 27

- 1 administers an immunization to any individual and provides data
- 2 elements to the department shall notify the individual or the
- 3 individual's legally authorized representative:
- 4 (1) that the individual's immunization information
- 5 will be included in the registry unless removal from the registry is
- 6 requested in accordance with the guidelines adopted under
- 7 Subsection (a); and
- 8 (2) of the procedures for requesting removal from the
- 9 registry. [The department shall verify consent before including
- 10 the information in the immunization registry. The department may
- 11 not retain individually identifiable information about ar
- 12 individual for whom consent cannot be verified.
- 13 (e) The department shall:
- 14 (1) make available on the department's Internet
- 15 website a printable form that states an individual's immunization
- 16 information will be included in the registry unless removal from
- 17 the registry is requested and that details the procedures for
- 18 submitting an electronic or written request for removal from the
- 19 registry [provide notice to a health care provider that submits an
- 20 immunization history for an individual for whom consent cannot be
- 21 verified. The notice shall contain instructions for obtaining
- 22 consent] in accordance with guidelines adopted under Subsection
- 23 (a)<u>; and</u>
- (2) make the form described by Subdivision (1)
- 25 available for distribution to health care providers [and
- 26 resubmitting the immunization history to the department].
- 27 (e-1) A health care provider may use the printable form

- 1 described by Subsection (e) to provide the notification required
- 2 under Subsection (d).
- 3 (1) Registry information may not be used to exclude any
- 4 individual from the receipt of any service during a natural or
- 5 man-made disaster unless the service is withheld because of a
- 6 medical contraindication.
- 7 (m) The department may not sell registry information to any
- 8 public or private entity.
- 9 SECTION 2. Section 161.00705(f), Health and Safety Code, is
- 10 amended to read as follows:
- 11 (f) Unless an individual or the individual's legally
- 12 authorized representative [consents] in writing or electronically
- 13 requests that [to continued inclusion of] the individual's
- 14 information be removed from  $[\frac{in}{in}]$  the registry, the department shall
- 15 <u>include</u> [<u>remove</u>] the immunization records collected under this
- 16 section in [from] the registry [on expiration of the period
- 17 prescribed under Subsection (e)].
- SECTION 3. Sections 161.0071(a) and (b), Health and Safety
- 19 Code, are amended to read as follows:
- 20 (a) The first time the department receives registry data for
- 21 an individual [for whom the department has received consent] to be
- 22 included in the registry, the department shall send notice to the
- 23 individual or the individual's legally authorized representative
- 24 disclosing:
- 25 (1) that providers and payors may be sending the
- 26 individual's immunization information to the department;
- 27 (2) the information that is included in the registry;

- 1  $\hspace{1cm}$  (3) the persons to whom the information may be
- 2 released under Sections 161.00735(b) and 161.008(d);
- 3 (4) the purpose and use of the registry;
- 4 (5) the procedure to exclude an individual from the
- 5 registry; and
- 6 (6) the procedure to report a violation if an
- 7 individual's information is included in the registry after
- 8 exclusion has been requested [or consent has been withdrawn].
- 9 (b) The [On discovering that consent to be included in the
- 10 registry has not been granted or has been withdrawn, the]
- 11 department shall exclude [the individual's immunization records]
- 12 from the registry and any other registry-related department record
- 13 that individually identifies the individual the immunization
- 14 record of any individual from whom a request for exclusion has been
- 15 received by the department.
- 16 SECTION 4. Section 161.0073, Health and Safety Code, is
- 17 amended by amending Subsection (a) and adding Subsections (e), (f),
- 18 (g), and (h) to read as follows:
- 19 (a) Except as provided by this section and Sections 161.007,
- 20 161.00705, 161.00706, [and] 161.00735, and 161.008, information
- 21 that individually identifies an individual that is received by the
- 22 department for the immunization registry is confidential and may be
- 23 used by the department for registry purposes only.
- 24 (e) The department may use registry information for
- 25 <u>internal public health research on approval of the department's</u>
- 26 institutional review board.
- 27 (f) The department may release registry information for

- 1 external public health research if:
- 2 (1) the individual or the individual's legally
- 3 <u>authorized representative submits a written authorization to the</u>
- 4 department for release of the individual's registry data;
- 5 (2) the department does not disclose individually
- 6 identifiable information; or
- 7 (3) the department's institutional review board
- 8 approves the release of individually identifiable information
- 9 subject to Subsection (g).
- 10 (g) The department's institutional review board may not
- 11 approve the release of individually identifiable information for a
- 12 research proposal unless the proposal includes a provision
- 13 requiring the proposal's researchers to obtain informed consent
- 14 from each individual or the individual's legally authorized
- 15 representative before the department releases the individual's
- 16 <u>registry data to the researchers.</u>
- 17 (h) The executive commissioner shall adopt rules to ensure
- 18 that the use or release of registry information under this
- 19 subchapter complies with all state and federal laws relating to the
- 20 privacy, protection, confidentiality, and transmission of health
- 21 <u>information</u>, including the Health Insurance Portability and
- 22 Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted
- 23 <u>under that Act.</u>
- SECTION 5. Sections 161.00735(c) and (h), Health and Safety
- 25 Code, are amended to read as follows:
- 26 (c) The department may receive immunization information
- 27 from a health authority of another state or from a local health

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- 1 authority in another state if the department determines that
- 2 residents of that state have evacuated or relocated to this state in
- 3 response to a disaster. The department shall include information
- 4 received under this subsection in the registry. [Notwithstanding
- 5 Section 161.007, the department is not required to obtain written
- 6 consent for the inclusion in the registry of information received
- 7 under this subsection.
- 8 (h) The executive commissioner shall make every effort to
- 9 enter into a memorandum of agreement with each state to which
- 10 residents of this state are likely to evacuate in a disaster on:
- 11 (1) the release to and use by [of registry information
- 12 under this section to] the appropriate health authority or local
- 13 health authority of that state of registry information under this
- 14 <u>section</u>[, including the length of time the information may be
- 15 retained by that state]; and
- 16 (2) the receipt and use of information submitted by
- 17 the health authority or local health authority of that state for
- 18 inclusion in the registry under this section.
- SECTION 6. Sections 161.008(c) and (e), Health and Safety
- 20 Code, are amended to read as follows:
- 21 (c) The department may obtain the data constituting an
- 22 immunization record for an individual from a public health
- 23 district, a local health department, the individual or the
- 24 individual's legally authorized representative, a physician to the
- 25 individual, a payor, or any health care provider licensed or
- 26 otherwise authorized to administer vaccines. [The department shall
- 27 verify consent before including the reported information in the

- 1 immunization registry. The department may not retain individually
- 2 identifiable information about an individual for whom consent
- 3 cannot be verified.
- 4 (e) An individual or the individual's legally authorized
- 5 representative may obtain and on request to the department shall be
- 6 provided with all individually identifiable immunization registry
- 7 information concerning the individual and information on the
- 8 procedure for requesting removal from the registry.
- 9 SECTION 7. Section 161.0095(a), Health and Safety Code, is
- 10 amended to read as follows:
- 11 (a) The department shall develop:
- 12 (1) continuing education programs for health care
- 13 providers relating to immunizations and the vaccines for children
- 14 program operated by the department under authority of 42 U.S.C.
- 15 Section 1396s; and
- 16 (2) educational information, for health care
- 17 providers, health care clinics, hospitals, and any other health
- 18 care facility that provides health care to children 14 to 18 years
- 19 of age, relating to the immunization registry and the option for an
- 20 individual or the individual's legally authorized representative
- 21 to request removal [who is 18 years of age or older to consent to
- 22 submission and retention] of the individual's information from [in]
- 23 the immunization registry.
- SECTION 8. Section 161.0107(c), Health and Safety Code, is
- 25 amended to read as follows:
- 26 (c) The executive commissioner by rule shall specify:
- 27 (1) the fields necessary to populate the immunization

- 1 registry[, including a field that indicates the patient's consent
- 2 to be listed in the immunization registry has been obtained]; and
- 3 (2) the data standards that must be used for
- 4 electronic submission of immunization information.
- 5 SECTION 9. The following provisions of the Health and
- 6 Safety Code are repealed:
- 7 (1) Sections 161.007(a-1), (a-3), (a-4), (a-5), and
- 8 (a-6);
- 9 (2) Sections 161.00705(e) and (h); and
- 10 (3) Sections 161.00735(e) and (f).
- 11 SECTION 10. (a) The changes in law made by this Act to
- 12 Subchapter A, Chapter 161, Health and Safety Code, apply to
- 13 immunization information received by the Department of State Health
- 14 Services before, on, or after January 1, 2019. An individual whose
- 15 immunization information was included immediately before January
- 16 1, 2019, in the immunization registry established under Subchapter
- 17 A, Chapter 161, Health and Safety Code, is subject to the changes in
- 18 law made by this Act to that subchapter, including the procedures
- 19 established by that subchapter as amended by this Act.
- 20 (b) The changes in law made by this Act do not authorize the
- 21 Department of State Health Services to include in the immunization
- 22 registry established under Subchapter A, Chapter 161, Health and
- 23 Safety Code, immunization information of an individual who is 18
- 24 years of age or older and whose immunization information was not
- 25 included in the registry on or before January 1, 2019, unless the
- 26 department receives immunization data from a health care provider
- 27 who:

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- 1 (1) administers an immunization to the individual
- 2 after that date and elects to provide the individual's immunization
- 3 information to the department; and
- 4 (2) notifies the individual before submission of the
- 5 information to the department:
- 6 (A) that the health care provider is providing
- 7 the information to the department for inclusion in the registry;
- 8 (B) that the information will remain in the
- 9 registry until removal is requested by the individual or the
- 10 individual's legally authorized representative; and
- 11 (C) of the procedures for requesting removal from
- 12 the registry under Subchapter A, Chapter 161, Health and Safety
- 13 Code, as amended by this Act.
- 14 SECTION 11. (a) As soon as practicable after the effective
- 15 date of this section, the Department of State Health Services shall
- 16 conduct a public awareness campaign to educate health care
- 17 providers, parents, payors, schools, and the public about the
- 18 changes in law made by this Act.
- 19 (b) As soon as practicable after the effective date of this
- 20 section, the executive commissioner of the Health and Human
- 21 Services Commission shall adopt the rules required by Section
- 22 161.0073(h), Health and Safety Code, as added by this Act.
- 23 SECTION 12. (a) Except as provided by Subsection (b) of this
- 24 section, this Act takes effect January 1, 2019.
- 25 (b) Section 11 of this Act takes effect September 1, 2017.